



Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

Manufacturer name	Ascensia Diabetes Care Holdings AG
Manufacturer address and contact details	Peter Merian-Strasse 90 4052 Basel Switzerland
Single Registration Number (SRN) (if available)	CH-MF-000034124

Authorised Representative name (if applicable)	Ascensia Diabetes Care Italy S.r.l.
Authorised Representative address and contact details	Via Varesina, 162 20156 Milano Italy
Single Registration Number (SRN) (if available)	IT-AR-000025584

Notified body name (if applicable)	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam. Netherlands
Notified body number (if applicable)	2797
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE711083
Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	31-December-2024
End date of extended validity/transition period	31-December-2027



We, as the manufacturer declare under our sole responsibility:

- for the **devices** listed in the attached schedule the conditions for the legal extension of timelines as required in Article 110.3a of the IVDR are met and
- for the **Directive Certificate** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met and
- the **devices** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificate (Original expiry date after 9 July 2024)** as listed above or in the attached schedule
 - Directive Certificate(s) covering the device(s) listed in the attached schedule was issued after 25 May 2017, was valid on 26 May 2022 and has not been withdrawn afterwards.
 - Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has been lodged to our notified body (2797). The reference numbers of the signed agreements are Q524332 and Q695245.
- **Quality Management System (QMS)**
 - QMS in accordance with Article 10(8) IVDR is in place.
 - Notified body (2797) has issued the attached certificate for the IVDR-compliant QMS (IVDR 745580).
- **Devices listed in the attached schedule**
 - The devices continue to comply with the IVDD.
 - There are no significant changes in the design and intended purpose.
 - The device do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.



Signed for and on behalf of the manufacturer:

Ascensia Diabetes Care Holdings AG
Basel, Switzerland
Jul 18, 2024

Signed by:

Jon Chambless

D1F5B4E1275F442...

Jon Chambless
Global Head of Regulatory and Quality

Signed by:

Brian S. Truchan

0BD78DC4A2BD498...

Brian Truchan
Head of Regulatory affairs Mature markets

DocuSigned by:

Caroline Bastidas

EE912643C3604AE...

Caroline Bastidas
Regulatory Affairs Manager, Europe

Email: ADC-Regulatory@ascensia.com



Schedule of Devices

The above Manufacturer’s Declaration is valid for the following devices:

Identification of the device(s)¹ (e.g., device name, family/group name device model or catalogue number)	End date of extended validity / transition period	Substitute Device(s) (if applicable)	Directive Certificate number to which this declaration is issued (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the IVDR application was lodged/contract signed (if applicable)
Contour Next One blood glucose meter	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour Plus One blood glucose meter	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour Next blood glucose test strips	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour Plus blood glucose test strips	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour Next controls	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour Plus controls	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour Care blood glucose meter	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour Care blood glucose test strips	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour Plus Blue blood glucose meter	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797

¹ for devices with IVDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above



Contour Plus Elite blood glucose meter	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour Next – connected- blood glucose meter	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour Plus blood glucose meter	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour XT blood glucose meter	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour blood glucose test strips	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour TS blood glucose test strips	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour controls	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Contour TS controls	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Ketostix	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797
Keto-Diastix	31-December-2027	N/A	CE 711083	31-December-2024	2797	2797

Declaration of Conformity

LEGAL MANUFACTURER:	Ascensia Diabetes Care Holdings AG Peter Merian-Strasse 90 4052 Basel Switzerland
EU AUTHORIZED REPRESENTATIVE:	Ascensia Diabetes Care Italy S.r.l. Via Varesina, 162 20156 Milano Italy
PLACE OF MANUFACTURE:	See page 2
PRODUCT CATEGORY:	System for Self-Testing of Blood Glucose
GMDN CODE:	Blood Glucose Meter: GMDN 62645 Blood Glucose Test Strips: GMDN 53307 Control Solution: GMDN 41819
PRODUCT:	Contour Next blood glucose monitoring system, consisting of: Contour Next Blood Glucose Meter (Connected meter) Contour Next Blood Glucose Test Strips Contour Next Controls
CLASSIFICATION:	List B according to Annex II of directive 98/79/EC
CONFORMITY ASSESSMENT ROUTE:	Annex IV , Excluding sections 4 and 6
NOTIFIED BODY:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Country : Netherlands Notified Body number : 2797
EC CERTIFICATE NUMBER:	CE 711083

We, Ascensia Diabetes Care Holdings AG, declare that the above-mentioned product(s) meet the provisions of :

- the Directive 98/79/EC Of The European Parliament And Of The Council on In Vitro Diagnostic medical devices
- the RED Directive (2014/53/EU) of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment <https://www.diabetes.ascensia.com/declarationofconformity/>
- the RoHS Directive (2011/65/EU) of the European Parliament of the Council of 8 June 2011 and RoHS 3 (EU 2015/863) on restriction of the use of certain hazardous substances in electrical and electronic equipment

The present EU Declaration of conformity is issued under sole responsibility of the manufacturer
The Manufacturer retains all supporting documentation.

2022-05-18
Basel, Switzerland



Pam Schaub

Head of Global Regulatory Affairs

Declaration of Conformity

PLACE OF MANUFACTURE:

**Contour Next (connected) Blood Glucose Meters
Manufacturing:**

PT PHC Indonesia
Kawasan Industri MM2100 Blok O-1
Cikarang Barat
Bekasi 17520
Indonesia

Contour Next Blood Glucose Test Strips Manufacturing:

PHC Corporation
In Vitro Diagnostics Division
2131-1 Minamigata
Toon, Ehime, 791-0395
Japan

Contour Next Controls Manufacturing:

Bionostics, Inc.
7 Jackson Road
Devens MA 01434
United States of America

Packaging Location:

RR Donnelley GTS Poland Sp. z o. o.
ul. Zakładowa 90/92
92-402 Lodz
Poland


Alternative packaging location (Strips):

RR Donnelley, Global Turnkey Solutions
1600 Disk Drive
Plover WI 54467
United States of America

Alternative packaging location (kits):

RR Donnelly Global Turnkey Solutions Mexico S.DE.R.L DE D.V.
Boulevard Internacional #881
San Jeronimo
Chihuahua, C.P. 32505
Mexico

2022-05-18
Basel, Switzerland



Pam Schaub
Head of Global Regulatory Affairs

Declaration of Conformity

Contour Next Control Solutions



CONFIGURATIONS:

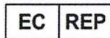


INTENDED USE:

Contour Next control solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes and by health care professionals as a quantitative quality check of your blood glucose monitoring system.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel
Switzerland
SRN : CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milano
Italy
SRN : IT-AR-000025584

PRODUCT CATEGORY:

Various diabetes monitoring instruments – consumables

GMDN:

41819

EMDN:

W020106019085

BASIC UDI-DI:

15016003CNCCB2P

RISK CLASS OF THE DEVICE:

Class C, Implementation Rule 1.6 (IVDR Annex VIII)

CONFORMITY ASSESSMENT ROUTE:

IVDR, Annex IX
Conformity Assessment based on a Quality Management System and Assessment of Technical Documentation

NOTIFIED BODY:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Country : Netherlands
Notified Body number : 2797

EC CERTIFICATE NUMBER:

IVDR 745580 (Annex IX Chapter I and III);
IVDR 745587 (Annex IX Chapter II)

APPLICABLE CS:

There is no applicable CS

22 June 2023
Basel, Switzerland

On behalf of Ascensia Diabetes Care Holdings AG



Larnie James
Technical Documentation Person Responsible for
Regulatory Compliance (EU IVDR Art 15 3(b))

Declaration of Conformity

We, Ascensia Diabetes Care Holdings AG, declare that the above-mentioned product(s) meet the provisions of:

- The European Regulation on In Vitro Diagnostic Medical Devices (2017/746), IVDR.

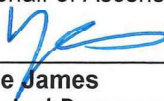
Other European legislations this product complies with:

- Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

The present EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.
The Manufacturer retains all supporting documentation.

22 June 2023
Basel, Switzerland

On behalf of Ascensia Diabetes Care Holdings AG



Larnie James
Technical Documentation Person Responsible for
Regulatory Compliance (EU IVDR Art 15 3(b))

Overensstemmelseserklæring

Contour Next-kontrolopløsninger



KONFIGURATIONER:

CONTROL	L	Lav
CONTROL	N	Normal
CONTROL	H	Høj

TILSIGTET BRUG:

Contour Next-kontrolopløsninger er vandige glukoseopløsninger beregnet til brug ved selvtestning af personer med diabetes og af sundhedspersonale som et kvantitativt kvalitetstjek af dit system til måling af blodsukker.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel
Schweiz
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milano
Italien
SRN: IT-AR-000025584

PRODUKTKATEGORI:

Diverse instrumenter til diabetesmonitorering – forbrugsartikler

GMDN:

41819

EMDN:

W020106019085

BASIS-UDI-DI:

15016003CNCCB2P

ANORDNINGENS RISIKOKLASSE:

Klasse C, implementeringsregel 1.6 (IVDR-bilag VIII)

RUTE FOR OVERENSSTEMMELSESVURDERING:

IVDR, bilag IX
Overensstemmelsesvurdering baseret på et kvalitetsstyringssystem og vurdering af teknisk dokumentation

BEMYNDIGET ORGAN:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Land: Holland
Nummer på bemyndiget organ: 2797

EF-CERTIFIKATNUMMER:

IVDR 745580 (bilag IX, kapitel I og III);
IVDR 745587 (bilag IX, kapitel II)

GÆLDENDE CS:

Der er intet gældende CS

14 september 2023
Basel, Schweiz

På vegne af Ascensia Diabetes Care Holdings AG

Larnie James

Person med ansvar for teknisk dokumentation samt for overholdelse af lovgivning (EU IVDR-artikel 15 3(b))

Overensstemmelseserklæring

Vi, Ascensia Diabetes Care Holdings AG, erklærer, at ovennævnte produkt(er) opfylder bestemmelserne i:

- den europæiske forordning om medicinsk udstyr til in vitro-diagnostik (2017/746), IVDR.

Anden europæisk lovgivning, som dette produkt overholder:

- Europa-Parlamentets og Rådets forordning (EF) nr. 1907/2006 af 18. december 2006 om registrering, vurdering, godkendelse og begrænsning af kemikalier (REACH)

Nærværende EU-overensstemmelseserklæring er udstedt under producentens eneansvar.

Producenten bevarer al understøttende dokumentation.

14 september 2023
Basel, Schweiz

På vegne af Ascensia Diabetes Care Holdings AG

Larnie James
Person med ansvar for teknisk dokumentation samt for
overholdelse af lovgivning (EU IVDR-artikel 15 3(b))

Konformitätserklärung

Contour Next Kontrollösungen



KONFIGURATIONEN:

CONTROL L Niedrig
CONTROL N Normal
CONTROL H Hoch

VERWENDUNGSZWECK:

Contour Next Kontrollösungen sind wässrige Glukoselösungen, die für die Verwendung zur Blutzucker-Selbstbestimmung durch Menschen mit Diabetes und Gesundheitsfachkräfte als quantitative Qualitätskontrolle Ihres Blutzuckermesssystems vorgesehen sind.



Ascensia Diabetes Care Holdings AG
Peter-Merian-Strasse 90
4052 Basel
Schweiz
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Mailand
Italien
SRN: IT-AR-000025584

PRODUKTKATEGORIE:

Verschiedene Diabeteskontrollgeräte – Verbrauchsmaterialien

GMDN:

41819

EMDN:

W020106019085

BASIS-UDI-DI:

15016003CNCCB2P

RISIKOKLASSE DES PRODUKTS:

Klasse C, Durchführungsvorschrift 1.6 (IVDR Anhang VIII)

KONFORMITÄTSMANAGEMENTVERFAHREN:

IVDR, Anhang IX
Konformitätsbewertung auf der Grundlage eines Qualitätsmanagementsystems und einer Bewertung der technischen Dokumentation

BENANNT STELLE:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Land: Niederlande
Nummer der benannten Stelle: 2797

NUMMER DES EG-ZERTIFIKATS:

IVDR 745580 (Anhang IX, Kapitel I und III);
IVDR 745587 (Anhang IX, Kapitel II)

ANWENDBARE GS:

Es gibt keine anwendbaren GS.

14 September 2023
Basel, Schweiz

Im Auftrag der Ascensia Diabetes Care Holdings AG

Larnie James
Für die technische Dokumentation zuständige und
für die Einhaltung der Regulierungsvorschriften
verantwortliche Person (EU IVDR Artikel 15 3(b))

Konformitätserklärung

Wir, die Ascensia Diabetes Care Holdings AG, erklären, dass das bzw. die oben genannte(n) Produkt(e) die Bestimmungen der folgenden Verordnung erfüllen:

- Europäische Verordnung über In-vitro-Diagnostika (EU 2017/746), IVDR.

Weitere europäische Rechtsvorschriften, denen dieses Produkt entspricht:

- Verordnung (EG) Nr. 1907/2006 des Europäischen Parlaments und des Rates vom 18. Dezember 2006 zur Registrierung, Bewertung, Zulassung und Beschränkung chemischer Stoffe (REACH)

Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller.
Der Hersteller bewahrt alle Begleitunterlagen auf.

14 September 2023
Basel, Schweiz

Im Auftrag der Ascensia Diabetes Care Holdings AG

Larnie James
Für die technische Dokumentation zuständige und
für die Einhaltung der Regulierungsvorschriften
verantwortliche Person (EU IVDR Artikel 15 3(b))

Δήλωση συμμόρφωσης

Διαλύματα ελέγχου Contour Next



ΔΙΑΜΟΡΦΩΣΕΙΣ:

CONTROL L	Χαμηλή
CONTROL N	Κανονική
CONTROL H	Υψηλή

ΠΡΟΟΡΙΖΟΜΕΝΗ ΧΡΗΣΗ:

Τα διαλύματα ελέγχου Contour Next είναι υδατικά διαλύματα γλυκόζης που προορίζονται για αυτομέτρηση από άτομα με διαβήτη και από επαγγελματίες υγείας, ως ποσοτικός έλεγχος ποιότητας για το σύστημα μέτρησης γλυκόζης του αίματος.



Ascensia Diabetes Care Holdings AG (Εταιρεία συμμετοχών Ascensia Diabetes Care AG)
Peter Merian-Strasse 90
4052 Βασιλεία
Ελβετία
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Μιλάνο
Ιταλία
SRN: IT-AR-000025584

ΚΑΤΗΓΟΡΙΑ ΠΡΟΪΟΝΤΟΣ:

Διάφορα όργανα παρακολούθησης του διαβήτη - αναλώσιμα

GMDN:

41819

EMDN:

W020106019085

ΒΑΣΙΚΟ UDI-DI:

15016003CNCCB2P

ΚΑΤΗΓΟΡΙΑ ΚΙΝΔΥΝΟΥ ΤΟΥ ΠΡΟΪΟΝΤΟΣ:

Κατηγορία C, Κανόνας εφαρμογής 1.6 (IVDR Παράρτημα VIII)

ΔΙΑΔΙΚΑΣΙΑ ΕΚΤΙΜΗΣΗΣ ΣΥΜΜΟΡΦΩΣΗΣ:

IVDR, Παράρτημα IX
Εκτίμηση συμμόρφωσης βάσει συστήματος διαχείρισης ποιότητας και εκτίμηση τεχνικής τεκμηρίωσης

ΚΟΙΝΟΠΟΙΗΜΕΝΟΣ ΟΡΓΑΝΙΣΜΟΣ:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Χώρα: Κάτω Χώρες
Αριθμός Κοινοποιημένου Οργανισμού: 2797

ΑΡΙΘΜΟΣ ΠΙΣΤΟΠΟΙΗΤΙΚΟΥ ΕΚ:

IVDR 745580 (Παράρτημα IX Κεφάλαιο I και III),
IVDR 745587 (Παράρτημα IX Κεφάλαιο II)

ΙΣΧΥΟΝ CS:

Δεν υπάρχει ισχύον CS

Εκ μέρους της Ascensia Diabetes Care Holdings AG

14 Σεπτεμβρίου 2023
Βασιλεία, Ελβετία

Larnie James
Υπεύθυνος Τεχνικής Τεκμηρίωσης για την Κανονιστική
Συμμόρφωση [Άρθρο 15 3(β) της ΕΕ για τον Κανονισμό IVDR]

Δήλωση συμμόρφωσης

Εμείς, η Ascensia Diabetes Care Holdings AG, δηλώνουμε ότι τα προαναφερθέντα προϊόντα συμμορφώνονται με τις απαιτήσεις:

- Του Ευρωπαϊκού Κανονισμού για τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα (2017/746), IVDR.

Άλλες Ευρωπαϊκές νομοθεσίες με τις οποίες συμμορφώνεται αυτό το προϊόν:

- Του Κανονισμού (ΕΚ) αρ. 1907/2006 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 18ης Δεκεμβρίου 2006 για την καταχώρηση, την αξιολόγηση, την αδειοδότηση και τους περιορισμούς των χημικών προϊόντων (REACH)

Η παρούσα δήλωση συμμόρφωσης ΕΕ εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή.

Ο Κατασκευαστής διαθέτει κάθε σχετική τεκμηρίωση.

14 Σεπτεμβρίου 2023
Βασιλεία, Ελβετία

Εκ μέρους της Ascensia Diabetes Care Holdings AG

Larnie James

Υπεύθυνος Τεχνικής Τεκμηρίωσης για την Κανονιστική
Συμμόρφωση [Άρθρο 15 3(β) της ΕΕ για τον Κανονισμό IVDR]

Declaración de conformidad

Soluciones control Contour Next



CONFIGURACIONES:



USO PREVISTO:

Las soluciones control Contour Next son soluciones acuosas de glucosa indicadas para el autodiagnóstico por personas con diabetes y por profesionales de la salud con el fin de realizar un control de calidad cualitativo de su sistema para monitorización de glucemia.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basilea
Suiza
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milán
Italia
SRN: IT-AR-000025584

CATEGORÍA DE PRODUCTO:

Diversos instrumentos de monitorización de la diabetes; consumibles

GMDN:

41819

EMDN:

W020106019085

UDI-DI BÁSICO:

15016003CNCCB2P

CLASE DE RIESGO DEL DISPOSITIVO:

Clase C, norma de aplicación 1.6 (IVDR, anexo VIII)

RUTA DE EVALUACIÓN DE CONFORMIDAD:

IVDR, anexo IX
Evaluación de conformidad basada en un sistema de gestión de calidad y evaluación de la documentación técnica

ORGANISMO NOTIFICADO:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Ámsterdam
País: Países Bajos
Número de organismo notificado: 2797

NÚMERO DE CERTIFICADO DE LA CE:

IVDR 745580 (anexo IX, capítulos I y III);
IVDR 745587 (anexo IX, capítulo II)

CS APLICABLE:

No hay CS aplicable

14 septiembre 2023
Basilea, Suiza

En nombre de Ascensia Diabetes Care Holdings AG

Larnie James
Responsable de Cumplimiento normativo de la
documentación técnica (IVDR de la UE, artículo 15 3[b])

Declaración de conformidad

Nosotros, Ascensia Diabetes Care Holdings AG, declaramos que el/los producto(s) arriba mencionado(s) cumple(n) con las disposiciones de:

- El Reglamento europeo sobre productos sanitarios para diagnóstico in vitro (2017/746), IVDR.

Otras legislaciones europeas con las que cumple este producto:

- Reglamento (CE) n.º 1907/2006 del Parlamento Europeo y del Consejo del 18 de diciembre de 2006 acerca del registro, evaluación, autorización y restricción de sustancias químicas (REACH)

La presente Declaración de conformidad de la UE se emite bajo la exclusiva responsabilidad del Fabricante. El Fabricante conserva todos los documentos complementarios.

14 septiembre 2023
Basilea, Suiza

En nombre de Ascensia Diabetes Care Holdings AG

Larnie James
Responsable de Cumplimiento normativo de la
documentación técnica (IVDR de la UE, artículo 15 3[b])

Vaatimustenmukaisuusvakuutus

Contour Next-kontrolliliuokset



MÄÄRITYKSET:

CONTROL	L	Matala
CONTROL	N	Normaali
CONTROL	H	Korkea

KÄYTTÖTARKOITUS:

Contour Next -kontrolliliuokset ovat vesipohjaisia glukoosiliuoksia, jotka on tarkoitettu käytettäväksi diabetesta sairastavien itsetestaukseen ja terveydenhuollon ammattilaisten käyttöön verengluukoosin seurantajärjestelmäsi kvantitatiivisessa laaduntarkastuksessa.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel
Sveitsi
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milano
Italia
SRN: IT-AR-000025584

TUOTELUOKKA:

Erilaiset diabeteksen seuraintinstrumentit – kulutustarvikkeet

GMDN:

41819

EMDN:

W020106019085

LAITE- JA VALMISTAJAKOHTAINEN PERUSLAITETUNNISTE (BASIC UDI-DI):

15016003CNCCB2P

LAITTEEN RISKILUOKKA:

Luokka C, käyttöönottosääntö 1.6 (IVDR-liite VIII)

VAATIMUSTENMUKAISUUDEN ARVIOINTIREITTI:

IVDR, liite IX
Vaatimustenmukaisuusarviointi laadunhallintajärjestelmän ja teknisen dokumentaation arvioinnin perusteella

ILMOITETTU LAITOS:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Maa: Alankomaat
Ilmoitetun laitoksen numero: 2797

EY-SERTIFIKAATTINUMERO:

IVDR 745580 (Liite IX luku I ja III);
IVDR 745587 (Liite IX luku II)

SOVELLETTAVA CS:

Ei sovellettavaa CS:ää

14 syyskuu 2023
Basel, Sveitsi

Ascensia Diabetes Care Holdings AG:n puolesta

Larnie James
Säännöstenmukaisuudesta vastaava tekninen
dokumentaatiohenkilö (EU IVDR artikla 15 3(b))

Vaatimustenmukaisuusvakuutus

Me, Ascensia Diabetes Care Holdings AG, vakuutamme, että yllä mainitut tuotteet täyttävät seuraavat vaatimukset:

- eurooppalainen in vitro -diagnostiikkaan tarkoitettuja lääkinnällisiä laitteita koskeva asetus (2017/746), IVDR.

Muut eurooppalaiset lait, joiden vaatimuksia tämä tuote noudattaa:

- Euroopan parlamentin ja neuvoston asetus (EY) N:o 1907/2006, annettu 18. päivänä joulukuuta 2006, kemikaalien rekisteröinnistä, arvioinnista, lupamenettelyistä ja rajoituksista (REACH).

Valmistaja antaa tämän EU:n vaatimustenmukaisuusvakuutuksen yksinomisella vastuullaan.

Valmistaja säilyttää kaiken tukidokumentaation.

14 syyskuu 2023
Basel, Sveitsi

Ascensia Diabetes Care Holdings AG:n puolesta

Larnie James
Säännöstenmukaisuudesta vastaava tekninen
dokumentaatiohenkilö (EU IVDR artikla 15 3(b))

Déclaration de conformité

Solutions de contrôle Contour Next



CONFIGURATIONS :



Basse



Normale



Élevée

UTILISATION PRÉVUE :

Les solutions de contrôle Contour Next sont des solutions de glucose aqueuses destinées à l'autosurveillance par les personnes diabétiques et par les professionnels de santé pour effectuer un contrôle qualité quantitatif de votre système d'autosurveillance glycémique.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Bâle
Suisse

SRN (SINGLE REGISTRATION NUMBER) : CH-MF-000034124



Ascensia Diabetes Care Italie S.r.l.
Via Varesina, 162
20156 Milan
Italie

SRN (SINGLE REGISTRATION NUMBER) : IT-AR-000025584

CATÉGORIE DE PRODUIT :

Divers instruments de surveillance du diabète — consommables

GMDN :

41819

EMDN :

W020106019085

UDI-DI DE BASE :

15016003CNCCB2P

CLASSE DE RISQUE DU DISPOSITIF :

Règle d'application 1.6 de la classe C, (Annexe VIII de l'IVDR)

VOIE D'ÉVALUATION DE LA CONFORMITÉ :

IVDR, ANNEXE IX
Évaluation de la conformité sur la base d'un système de gestion de la qualité et de l'évaluation de la documentation technique

ORGANISME NOTIFIÉ :

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Pays : Pays-Bas
Numéro de l'Organisme notifié : 2797

NUMÉRO DE CERTIFICAT CE :

IVDR 745580 (Chapitres I et III de l'Annexe IX) ;
IVDR 745587 (Chapitre II de l'Annexe IX)

CS APPLICABLE

Aucun CS n'est applicable

14 septembre 2023
Bâle, Suisse

Au nom d'Ascensia Diabetes Care Holdings AG

Larnie James
Personne de la Documentation technique en charge de
la Conformité réglementaire (IVDR UE Article 15 3(b))

Déclaration de conformité

Nous, Ascensia Diabetes Care Holdings AG, déclarons que le ou les produits susmentionnés sont conformes au :

- Règlement européen sur les dispositifs médicaux de diagnostic in vitro (2017/746), IVDR.

Autres législations européennes auxquelles ce produit est conforme :

- Règlement (CE) n° 1907/2006 du Parlement européen et du Conseil du 18 décembre 2006 concernant l'enregistrement, l'évaluation et l'autorisation des substances chimiques, ainsi que les restrictions applicables à ces substances (REACH).

La présente déclaration de conformité UE est délivrée sous la seule responsabilité du fabricant.

Le fabricant conserve tous les documents justificatifs.

14 septembre 2023
Bâle, Suisse

Au nom d'Ascensia Diabetes Care Holdings AG

Larnie James
Personne de la Documentation technique en charge de
la Conformité réglementaire (IVDR UE Article 15 3(b))

Izjava o sukladnosti

Kontrolne otopine Contour Next



KONFIGURACIJE:

CONTROL L Niska vrijednost

CONTROL N Normalna vrijednost

CONTROL H Visoka vrijednost

NAMJENA:

Kontrolne otopine Contour Next vodene su otopine glukoze namijenjene za samokontrolu koju provode osobe s dijabetesom i za kvantitativnu provjeru kvalitete sustava za mjerenje glukoze u krvi koju provode liječnici.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel
Švicarska

Jedinstveni registracijski broj (SRN): CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milano
Italija

Jedinstveni registracijski broj (SRN): IT-AR-000025584

KATEGORIJA PROIZVODA:

Razni instrumenti za mjerenje dijabetesa – potrošni materijal

GMDN:

41819

EMDN:

W020106019085

OSNOVNI UDI-DI:

15016003CNCCB2P

KLASA RIZIKA PROIZVODA:

Klasa C, provedbeno pravilo 1.6 (Prilog VIII. Uredbi IVDR)

NAČIN OCJENE SUKLADNOSTI:

IVDR, Prilog IX.

Ocjnjivanje sukladnosti na temelju sustava upravljanja kvalitetom i ocjenjivanja tehničke dokumentacije

PRIJAVLJENO TIJELO:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Država: Nizozemska
Broj prijavljenog tijela: 2797

BROJ EZ POTVRDE:

IVDR 745580 (Prilog IX., poglavlje I. i III.),
IVDR 745587 (Prilog IX., poglavlje II.)

PRIMJENJIVA ZAJEDNIČKA SPECIFIKACIJA (CS):

Ne postoji primjenjiva zajednička specifikacija (CS)

14 rujan 2023
Basel, Švicarska

U ime društva Ascensia Diabetes Care Holdings AG

Larnie James

Osoba za tehničku dokumentaciju odgovorna za usklađenost s propisima (EU IVDR članak 15., stavak 3., točka (b))

Izjava o sukladnosti

Mi, društvo Ascensia Diabetes Care Holdings AG, izjavljujemo da navedeni proizvod ispunjava odredbe:

- europske Uredbe o in vitro dijagnostičkim medicinskim proizvodima (2017/746), IVDR.

Ostali europski pravni propisi s kojima je proizvod sukladan:

- Uredba (EZ) br. 1907/2006 Europskog parlamenta i Vijeća od 18. prosinca 2006. o registraciji, evaluaciji, autorizaciji i ograničavanju kemikalija (REACH)

Ova EU izjava o sukladnosti izdaje se na isključivu odgovornost proizvođača.

Proizvođač zadržava svu popratnu dokumentaciju.

14 rujan 2023
Basel, Švicarska

U ime društva Ascensia Diabetes Care Holdings AG

Larnie James
Osoba za tehničku dokumentaciju odgovorna za usklađenost
s propisima (EU IVDR članak 15., stavak 3., točka (b))

Samræmisýfirlýsing

Contour Next-samanburðarlausnir



GRUNNUPPLÝSINGAR:

CONTROL L Lítil

CONTROL N Miðlungs

CONTROL H Mikil

FYRIRHUGUÐ NOTKUN:

Contour Next-samanburðarlausnir eru vatnsblandaðar glúkósalausnir sem ætlaðar eru einstaklingum með sykursýki til sjálfspöfunar og heilbrigðisstarfsfólki til gæðaathugana á blóðsykursmælingakerfinu.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel,
Sviss

STAKT SKRÁNINGARNÚMER (SRN): CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina 162
20156 Mílan,
Ítalíu

STAKT SKRÁNINGARNÚMER (SRN): IT-AR-000025584

VÖRUFLOKKUR:

Ýmis tæki til eftirlits með sykursýki – rekstrarvörur

GMDN-kóði:

41819

EMDN-kóði:

W020106019085

Almennt einkvæmt auðkenni tækis, auðkenni tækis (UDI-DI):

15016003CNCCB2P

ÁHÆTTUFLOKKUR TÆKIS:

Flokkur C, framkvæmdarregla 1,6 (IVDR, viðauki VIII)

SAMRÆMISMATSFERLI:

IVDR, viðauki IX
Samræmismat byggt á gæðastjórnunarkerfi og mati á tækniskjöllum

TILKYNNTUR AÐILI:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Land: Holland
Númer tilkynnts aðila: 2797

NÚMER EB-VOTTORDS:

IVDR 745580 (I. og III. kafli IX. viðauka),
IVDR 745587 (II. kafli IX. viðauka)

VIÐEIGANDI CS:

Ekkert viðeigandi CS

Fyrir hönd Ascensia Diabetes Care Holdings AG.

14 september 2023
Basel, Sviss

Larnie James
Tækniskjöl aðila sem ber ábyrgð á reglufylgni
(ESB IVDR b-liður 3. mgr. 15 gr.)

Samræmisýfirlýsing

Við, Ascensia Diabetes Care Holdings AG, lýsum því yfir að ofangreind(ar) vara/vörur uppfylla kröfur samkvæmt:

- Reglugerð Evrópusambandsins um lækningatæki til sjúkdómsgreiningar í glasi (2017/746), IVDR.

Önnur evrópsk löggjöf sem þessi vara samræmist:

- Reglugerð (EB) Evrópuþingsins og ráðsins nr. 1907/2006 frá 18. desember 2006 um skráningu, mat, leyfisveitingu og takmarkanir á íðefnum (REACH).

Þessi ESB-samræmisýfirlýsing er gefin út á ábyrgð framleiðanda.

Framleiðandi heldur eftir öllum gögnum þessu til staðfestingar.

14 september 2023
Basel, Sviss

Fyrir hönd Ascensia Diabetes Care Holdings AG.

Larnie James
Tækniskjöl aðila sem ber ábyrgð á reglufylgni
(ESB IVDR b-liður 3. mgr. 15 gr.)

Dichiarazione di conformità

Soluzioni di controllo Contour Next



CONFIGURAZIONI:

CONTROL L Basso

CONTROL N Normale

CONTROL H Alto

USO PREVISTO:

Le soluzioni di controllo Contour Next sono soluzioni acquose di glucosio destinate all'autocontrollo da parte di persone con diabete e di operatori sanitari come controllo quantitativo della qualità del sistema di monitoraggio della glicemia.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basilea
Svizzera
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milano
Italia
SRN: IT-AR-000025584

CATEGORIA DEL PRODOTTO:

Vari strumenti di monitoraggio del diabete – materiali di consumo

GMDN:

41819

EMDN:

W020106019085

UDI-DI DI BASE:

15016003CNCCB2P

CLASSE DI RISCHIO DEL DISPOSITIVO:

Classe C, regola di implementazione 1.6 (IVDR Allegato VIII)

PERCORSO DI VALUTAZIONE DELLA CONFORMITÀ:

IVDR, allegato IX
Valutazione della conformità basata su un sistema di gestione della qualità e sulla valutazione della documentazione tecnica

ORGANISMO NOTIFICATO:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Paese: Paesi Bassi
Numero organismo notificato: 2797

NUMERO DI CERTIFICATO CE:

IVDR 745580 (Allegato IX capitolo I e III);
IVDR 745587 (Allegato IX capitolo II);

SC APPLICABILI:

SC applicabili non presenti

14 settembre 2023
Basilea, Svizzera

Per conto di Ascensia Diabetes Care Holdings AG

Larnie James
Persona addetta alla documentazione tecnica responsabile
del rispetto della normativa (IVDR UE, articolo 15 3(b))

Dichiarazione di conformità

Noi, Ascensia Diabetes Care Holdings AG, dichiariamo che il(i) prodotto(i) sopraccitato(i) è conforme alle disposizioni del:

- Regolamento europeo relativo ai dispositivi medico-diagnostici in vitro (2017/746).

Altre normative europee cui questo prodotto è conforme:

- Regolamento (CE) N. 1907/2006 del Parlamento Europeo e del Consiglio del 18 dicembre 2006 concernente la registrazione, la valutazione, l'autorizzazione e la restrizione delle sostanze chimiche (REACH)

La presente Dichiarazione di conformità UE è rilasciata sotto la responsabilità esclusiva del produttore. Il produttore conserva tutta la documentazione di supporto.

14 settembre 2023
Basilea, Svizzera

Per conto di Ascensia Diabetes Care Holdings AG

Larnie James
Persona addetta alla documentazione tecnica responsabile
del rispetto della normativa (IVDR UE, articolo 15 3(b))

Samsvarserklæring

Contour Next kontrolløsninger



KONFIGURASJONER:

CONTROL	L	Lav
CONTROL	N	Normal
CONTROL	H	Høy

TILTENKT BRUK:

Contour Next kontrolløsninger er vandige glukoseløsninger tiltenkt for bruk i egenmåling av personer med diabetes og av helsepersonell som en kvantitativ kvalitetskontroll av ditt målesystem for blodsukker.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel
Sveits
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milano
Italia
SRN: IT-AR-000025584

PRODUKTKATEGORI:

Diverse instrumenter for diabetesmonitorering – forbruksartikler

GMDN:

41819

EMDN:

W020106019085

GRUNNLEGGENDE UDI-DI:

15016003CNCCB2P

ENHETENS RISIKOKLASSE:

Klasse C, implementeringsregel 1.6 (IVDR vedlegg VIII)

RUTE FOR SAMSVARSVURDERING:

IVDR, vedlegg IX
Samsvarsvurdering basert på et kvalitetsstyringssystem og vurdering av teknisk dokumentasjon

TEKNISK KONTROLLORGAN:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Land: Nederland
Teknisk kontrollorgannr.: 2797

CE-SERTIFIKATNUMMER:

IVDR 745580 (vedlegg IX, kapittel I og III);
IVDR 745587 (vedlegg IX, kapittel II)

GJELDENDE SERTIFISERINGSSTANDARD:

Ingen gjeldende sertifiseringsstandard

14 september 2023
Basel, Sveits

På vegne av Ascensia Diabetes Care Holdings AG

Larnie James
Ansvarlig for teknisk dokumentasjon og overholdelse
av regelverk (EU IVDR artikkel 15, nr. 3 (b))

Samsvarserklæring

Vi, Ascensia Diabetes Care Holdings AG, erklærer at ovennevnte produkt(er) oppfyller bestemmelsene i:

- EUs forordning om medisinsk utstyr for in vitro-diagnostikk (2017/746), IVDR.

Annen europeisk lovgivning dette produktet etterlever:

- Europaparlaments- og rådsforordning (EF) nr. 1907/2006 av 18. desember 2006 om registrering, vurdering og godkjenning av samt begrensninger for kjemikalier (REACH)

Denne EU-samsvarserklæringen er utstedt under produsentens eneansvar.

Produsenten beholder all støttedokumentasjon.

14 september 2023
Basel, Sveits

På vegne av Ascensia Diabetes Care Holdings AG

Larnie James
Ansvarlig for teknisk dokumentasjon og overholdelse
av regelverk (EU IVDR artikkel 15, nr. 3 (b))

Conformiteitsverklaring

Contour Next-controlebloedglucose



CONFIGURATIES:

CONTROL	L	Laag
CONTROL	N	Normaal
CONTROL	H	Hoog

BEOOGD GEBRUIK:

Contour Next-controlebloedglucose zijn oplossingen van glucose in water bestemd voor zelftesten door personen met diabetes en door medische zorgverleners als een kwaliteitscontrole van uw bloedglucosemeter.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Bazel
Zwitserland
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milaan
Italië
SRN: IT-AR-000025584

PRODUCTCATEGORIE:

Verschiede instrumenten voor diabetesmonitoring – verbruiksartikelen

GMDN:

41819

EMDN:

W020106019085

BASIS UDI-DI:

15016003CNCCB2P

RISICOKLASSE VAN HET INSTRUMENT:

Klasse C, uitvoeringsregel 1.6 (IVDR Annex VIII)

CONFORMITEITSBEOORDELINGSROUTE:

IVDR, annex IX
Conformiteitsbeoordeling op basis van een kwaliteitsbeheersysteem en beoordeling van technische documentatie

AANGEMELDE INSTANTIE:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Land: Nederland
Nummer aangemelde instantie: 2797

EC-CERTIFICAATNUMMER:

IVDR 745580 (Annex IX hoofdstuk I en III);
IVDR 745587 (Annex IX hoofdstuk II)

CS VAN TOEPASSING:

Er is geen CS van toepassing

14 september 2023
Bazel, Zwitserland

Namens Ascensia Diabetes Care Holdings AG

Larnie James
Verantwoordelijke (technische documentatie) voor
naleving van regelgeving (EU IVDR artikel 15 3(b))

Conformiteitsverklaring

Wij, Ascensia Diabetes Care Holdings AG, verklaren dat de bovengenoemde producten voldoen aan de bepalingen van:

- De Europese verordening inzake medische hulpmiddelen voor in-vitrodiagnostiek (2017/746), IVDR.

Overige Europese wetgeving waaraan dit product voldoet:

- Verordening (EC) 1907/2006 van het Europese Parlement en van de Europese Raad, 18 december 2006, inzake de registratie, evaluatie, autorisatie en beperking van chemische stoffen (REACH)

Deze EU-conformiteitsverklaring wordt uitgegeven onder de exclusieve verantwoordelijkheid van de fabrikant.

De fabrikant bewaart alle ondersteunende documentatie.

14 september 2023
Bazel, Zwitserland

Namens Ascensia Diabetes Care Holdings AG

Larnie James
Verantwoordelijke (technische documentatie) voor
naleving van regelgeving (EU IVDR artikel 15 3(b))

Deklaracja zgodności

Roztwory kontrolne Contour Next



KONFIGURACJE:

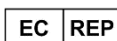
CONTROL	L	Niski
CONTROL	N	Prawidłowy
CONTROL	H	Wysoki

PRZEZNACZENIE:

Roztwory kontrolne Contour Next są wodnymi roztworami glukozy przeznaczonymi do używania przez osoby chore na cukrzycę badające się samodzielnie oraz przez personel medyczny w charakterze ilościowej kontroli jakości systemu monitorowania stężenia glukozy we krwi.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel
Szwajcaria
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milano
Włochy
SRN: IT-AR-000025584

KATEGORIA PRODUKTÓW:

Różne przyrządy do monitorowania cukrzycy — materiały zużywalne

GMDN:

41819

EMDN:

W020106019085

BASIC UDI-DI:

15016003CNCCB2P

KLASA RYZYKA WYROBU:

Klasa C, zgodnie z punktem 1.6 (Rozporządzenie w sprawie wyrobów medycznych do diagnostyki in vitro, Załącznik VIII)

DROGA OCENY ZGODNOŚCI:

Rozporządzenie w sprawie wyrobów medycznych do diagnostyki in vitro, Załącznik IX
Ocena zgodności na podstawie systemu zarządzania jakością i oceny dokumentacji technicznej

JEDNOSTKA NOTYFIKOWANA:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Kraj: Holandia
Numer jednostki notyfikowanej: 2797

NR CERTYFIKATU WE:

IVDR 745580 (Załącznik IX, Rozdziały I i III);
IVDR 745587 (Załącznik IX, Rozdział II)

MAJĄCE ZASTOSOWANIE WSPÓLNE SPECYFIKACJE:

Brak mających zastosowanie wspólnych specyfikacji

14 września 2023
Bazylea, Szwajcaria

W imieniu Ascensia Diabetes Care Holdings AG

Larnie James
Osoba zapewniająca dokumentację techniczną odpowiedzialna za zgodność regulacyjną (art. 15 punkt 3(b) Rozporządzenia UE w sprawie wyrobów medycznych do diagnostyki in vitro)

Deklaracja zgodności

My, Ascensia Diabetes Care Holdings AG, deklarujemy, że wymieniony(-ne) wyżej produkt(y) jest/są zgodny(-ne) z postanowieniami:

- Rozporządzenia Parlamentu Europejskiego i Rady (UE) 2017/746 w sprawie wyrobów medycznych do diagnostyki in vitro, IVDR

Pozostałe przepisy europejskie, z którymi ten produkt jest zgodny:

- Rozporządzenie (WE) nr 1907/2006 Parlamentu Europejskiego i Rady z dnia 18 grudnia 2006 r. w sprawie rejestracji, oceny, udzielania zezwoleń i stosowanych ograniczeń w zakresie chemikaliów (REACH)

Niniejsza Deklaracja zgodności UE zostaje wydana na wyłączną odpowiedzialność producenta.

Producent posiada wszelką dokumentację towarzyszącą.

14 września 2023
Bazylea, Szwajcaria

W imieniu Ascensia Diabetes Care Holdings AG

Larnie James
Osoba zapewniająca dokumentację techniczną odpowiedzialna za zgodność regulacyjną (art. 15 punkt 3(b) Rozporządzenia UE w sprawie wyrobów medycznych do diagnostyki in vitro)

Declaração de conformidade

Soluções de controlo Contour Next



CONFIGURAÇÕES:

CONTROL L Baixo

CONTROL N Normal

CONTROL H Alto

UTILIZAÇÃO PREVISTA:

As soluções de controlo Contour Next são soluções aquosas de glicose destinadas a serem utilizadas em autocontrolo por pessoas com diabetes e por profissionais de saúde como um controlo de qualidade quantitativo do seu sistema de monitorização da glicemia.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel
Suíça
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milano
Itália
SRN: IT-AR-000025584

CATEGORIA DO PRODUTO:

Vários instrumentos de monitorização da diabetes – consumíveis

GMDN:

41 819

EMDN:

W020106019085

UDI-DI BÁSICO:

15016003CNCCB2P

CLASSE DE RISCO DO DISPOSITIVO:

Classe C, Regra de implementação 1.6 (Anexo VIII do RDIV)

MEIO DE AVALIAÇÃO DA CONFORMIDADE:

RDIV, Anexo IX
Avaliação da conformidade com base no sistema de gestão da qualidade e na avaliação da documentação técnica

ORGANISMO NOTIFICADO:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
País: Países Baixos
Número do organismo notificado: 2797

NÚMERO DO CERTIFICADO CE:

RDIV 745580 (Anexo IX, Capítulo I e III);
RDIV 745587 (Anexo IX, Capítulo II)

CS APLICÁVEL:

Não existe um CS aplicável

14 setembro 2023
Basel, Suíça

Em nome da Ascensia Diabetes Care Holdings AG

Larnie James
Responsável de documentação técnica pela
conformidade regulamentar (RDIV UE, Artigo 15.º, 3[b])

Declaração de conformidade

A Ascensia Diabetes Care Holdings AG declara que o(s) produto(s) supramencionado(s) cumpre(m) as disposições do:

- Regulamento europeu relativo aos dispositivos médicos para diagnóstico in vitro (2017/746), RDIV.

Outras legislações europeias com as quais este produto está em conformidade:

- Regulamento (CE) n.º 1907/2006 do Parlamento Europeu e do Conselho, de 18 de dezembro de 2006, relativo a registo, avaliação, autorização e restrição de substâncias químicas (REACH)

A presente Declaração de conformidade da UE foi emitida sob a responsabilidade exclusiva do fabricante.
O fabricante retém toda a documentação de apoio.

14 setembro 2023
Basel, Suíça

Em nome da Ascensia Diabetes Care Holdings AG

Larnie James
Responsável de documentação técnica pela
conformidade regulamentar (RDIV UE, Artigo 15.º, 3[b])

Izjava o skladnosti

Kontrolne tekočine Contour Next



KONFIGURACIJE:

CONTROL L Nizka vrednost

CONTROL N Normalna vrednost

CONTROL H Visoka vrednost

NAMEN UPORABE:

Kontrolne tekočine Contour Next so vodne raztopine glukoze, namenjene za uporabo pri samokontroli s strani ljudi s sladkorno boleznijo in zdravstvenih delavcev kot kvantitativno preverjanje kakovosti vašega sistem za merjenje glukoze v krvi.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel
Švica
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milano
Italija
SRN: IT-AR-000025584

KATEGORIJA IZDELKA:

Različni instrumenti za spremljanje sladkorne bolezni – potrošni materiali

GMDN:

41819

EMDN:

W020106019085

OSNOVNI UDI-DI:

15016003CNCCB2P

RAZRED TVEGANJA PRIPOMOČKA:

Razred C, implementacijsko pravilo 1.6 (IVDR, priloga VIII)

POT UGOTAVLJANJA SKLADNOSTI:

IVDR, priloga IX
Ugotavljanje skladnosti na podlagi sistema za zagotavljanje kakovosti in presoje tehnične dokumentacije

PRIGLAŠENI ORGAN:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Država: Nizozemska
Številka priglšenega organa: 2797

ŠTEVILKA POTRDILA ES:

IVDR 745580 (priloga IX, poglavje I in III);
IVDR 745587 (priloga IX, poglavje II)

VELJAVNA CS:

Ni veljavne CS

V imenu družbe Ascensia Diabetes Care Holdings
AG

14 september 2023
Basel, Švica

Larnie James
Oseba za tehnično dokumentacijo, odgovorna za
skladnost s predpisi (EU IVDR, člen 15 3(b))

Izjava o skladnosti

Družba Ascensia Diabetes Care Holdings AG izjavlja, da zgoraj omenjeni izdelek(-i) izpolnjuje(-jo) določbe:

- Evropske uredbe o in vitro diagnostičnih medicinskih pripomočkih (2017/746), IVDR.

Druge evropske zakonodaje, s katerimi je ta izdelek skladen:

- Uredba (ES) št. 1907/2006 Evropskega parlamenta in Sveta z dne 18. decembra 2006 o registraciji, evalvaciji, avtorizaciji in omejevanju kemikalij (REACH)

Izjava EU o skladnosti je izdana na izključno odgovornost proizvajalca.

Proizvajalec hrani vso spremljajočo dokumentacijo.

14 september 2023
Basel, Švica

V imenu družbe Ascensia Diabetes Care Holdings
AG

Larnie James
Oseba za tehnično dokumentacijo, odgovorna za
skladnost s predpisi (EU IVDR, člen 15 3(b))

Försäkran om överensstämmelse

Contour Next-kontrollösningar



KONFIGURERINGAR:

CONTROL L Lågt

CONTROL N Normalt

CONTROL H Högt

AVSEDD ANVÄNDNING:

Contour Next-kontrollösningar är vattenbaserade glukoslösningar avsedda för användning vid självtestning av personer med diabetes samt av sjukvårdspersonal för kvantitativ kvalitetskontroll av ditt system för blodsockerkontroll.



Ascensia Diabetes Care Holdings AG
Peter Merian-Strasse 90
4052 Basel
Schweiz
SRN: CH-MF-000034124



Ascensia Diabetes Care Italy S.r.l.
Via Varesina, 162
20156 Milano
Italien
SRN: IT-AR-000025584

PRODUKTKATEGORI:

Olika instrument för övervakning av diabetes – förbrukningsvaror

GMDN:

41819

EMDN:

W020106019085

GRUNDLÄGGANDE UDI-DI:

15016003CNCCB2P

ENHETENS RISKKLASS:

Klass C, genomföranderegulering 1.6 (IVDR bilaga VIII)

FÖRFARANDE FÖR KONFORMITETSBEDÖMNING:

IVDR, bilaga IX
Konformitetsbedömning baserad på ett kvalitetsledningssystem och bedömning av teknisk dokumentation

ANMÄLT ORGAN:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Land: Nederländerna
Anmält organs nummer: 2797

EG-CERTIFIKATNUMMER:

IVDR 745580 (bilaga IX kapitel I och III);
IVDR 745587 (bilaga IX kapitel II);

TILLÄMPLIG CS:

Det finns ingen tillämplig CS

På uppdrag av Ascensia Diabetes Care Holdings AG

14 september 2023
Basel, Schweiz

Larnie James
Person inom teknisk dokumentation som är ansvarig
för regelefterlevnad (EU IVDR art. 15 3(b))

Försäkran om överensstämmelse

Vi, Ascensia Diabetes Care Holdings AG, intygar att ovan nämnda produkter uppfyller bestämmelserna i:

- Europeiska förordningen om medicintekniska produkter för in vitro-diagnostik (2017/746), IVDR.

Övrig europeisk lagstiftning som denna produkt uppfyller:

- Europaparlamentets och rådets förordning (EG) nr 1907/2006 av den 18 december 2006 om registrering, utvärdering, godkännande och begränsning av kemikalier (REACH)

Denna EU-försäkran om överensstämmelse utfärdas på tillverkarens eget ansvar.

Tillverkaren behåller all styrkande dokumentation.

14 september 2023
Basel, Schweiz

På uppdrag av Ascensia Diabetes Care Holdings AG

Larnie James
Person inom teknisk dokumentation som är ansvarig
för regelefterlevnad (EU IVDR art. 15 3(b))